

Response Under 37 C.F.R. § 41.37
Appellants' Brief
Application No. 10/786,725
Paper Dated: February 1, 2010
Attorney Docket No. 3896-031736 (P-6004)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application No. : 10/786,725 Confirmation No. 2750
Appellants : KIRK D. SWENSON et al.
Filed : February 25, 2004
Title : SAFETY BLOOD COLLECTION HOLDER
Group Art Unit : 3736
Examiner : Rene T. Towa
Customer No. : 32182

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Sir:

This Appeal Brief is submitted in support of the Notice of Appeal electronically submitted and received by the Patent Office on June 9, 2009 and the Notice of Panel Decision from Pre-Appeal Brief Review mailed on September 1, 2009. The Notice of Appeal appeals the final rejection of claims 1-9.

The Notice of Panel Decision from Pre-Appeal Brief Review set the time for filing an Appeal Brief as one month from the mailing of the Decision of September 1, 2009, namely, October 1, 2009. Pursuant to the provisions of 37 C.F.R. § 1.136(a) and MPEP § 1205.01, a four-month Petition for Extension of Time is submitted herewith, extending the period for reply until February 1, 2010.

The headings used hereinafter and the subject matter set forth under each heading are in accordance with 37 C.F.R. § 41.37.

I hereby certify that this correspondence is being electronically submitted to the United States Patent and Trademark Office on February 1, 2010.

02/01/2010

Date

Signature

Lisa R. McNany

Typed Name of Person Signing Certificate

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I. REAL PARTY IN INTEREST

Becton, Dickinson and Company, having its principal place of business at 1 Becton Drive, Franklin Lakes, NJ 07417, is the Assignee of the entire right, title, and interest to the above-identified application and, as such, is the real party in interest in this Appeal.

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II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences known to the Appellants, the Appellants' legal representative, or the Assignee of the above-identified application, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending Appeal.

III. STATUS OF CLAIMS

Claims 1-9 are currently pending in this application. Claim 1 is the sole independent claim. Claims 10-38 have been cancelled. Accordingly, claims 10-38 are not at issue in this Appeal.

Claims 1-2, 5-6, and 9 are finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Hollister (United States 5,277,311, hereinafter "Hollister '311") in view of Hollister (United States 4,982,842, hereinafter "Hollister '842").

Claims 3-4 are finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Hollister '311 in view of Hollister '842, and further in view of Kobayashi (United States 6,695,819, hereinafter "Kobayashi").

Claims 3-4 are finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Hollister '311 in view of Hollister '842, and further in view of Newby et al. (United States 6,440,104, hereinafter "Newby").

Claim 7 is finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Hollister '311 in view of Hollister '842, Newby, and further in view of Alesi et al. (United States 2003/0028152, hereinafter "Alesi").

Claim 7 is finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Hollister '311 in view of Hollister '842, Kobayashi, and further in view of Alesi.

Claim 8 is finally rejected under 35 U.S.C. § 103(a) as being unpatentable over Hollister '311 in view of Hollister '842, and further in view of Gyure et al. (United States 5,681,295, hereinafter "Gyure").

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IV. STATUS OF AMENDMENTS

Claims 1-9 were rejected in the final Office Action dated February 10, 2009. An Amendment After Final Rejection was filed on April 9, 2009. This Amendment After Final Rejection did not amend claims 1-9, but rather submitted one new independent claim and two dependent claims clarifying subject matter originally set forth in dependent claim 5. The Amendment After Final Rejection was not entered. Accordingly, this Appeal Brief is directed to claims 1-9, as rejected in the final Office Action dated February 10, 2009.

A Pre-Appeal Brief Request for Review was filed on June 9, 2009. The Notice of Panel Decision dated September 1, 2009 stated that the application should proceed to the Board of Patent Appeals and Interferences for further review.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The following is a summary of the claims currently under appeal. The present invention is directed to a safety needle holder assembly having a safety shield which is rotatable about the holder housing. The holder has a forward end including a needle receiving port for receiving a needle cannula therein and an annular skirt extending about the needle receiving port. The safety shield is pivotably attached to a collar wherein the collar is received between the annular skirt and the needle receiving port of the holder housing such that the safety shield is capable of being pivoted over at least a portion of a needle received within the needle receiving port of the holder housing. The annular skirt helps prevent the disconnection/dislocation of the collar from the housing holder through accidental force. The safety shield and the collar are axially rotatable with respect to the holder housing about an axis of the holder housing, such that the safety shield and the collar can be radially rotated to a desired position around a needle received within the needle receiving port and around the axis of the holder housing without axial movement of the collar along the axis. The collar is secured to the annular skirt via an interface fit, such as with a groove/protrusion arrangement, so that the shield pivots with respect to this annular skirt.

Independent claim 1 is directed to a holder assembly comprising a holder housing (10) adapted to receive a sample collection tube within a rearward end (11); a forward end (12) of the holder housing including a needle receiving port (15) for receiving a needle cannula (20) therein and an annular skirt (18) extending about the needle receiving port (15) (Figs. 7-8; page 6, lines 1-22; paragraphs [0031]-[0033]); and a safety shield (50) pivotably attached to a collar (30), said collar having an opening therethrough for receiving the needle cannula (20) therethrough, the collar (30) being received between the annular skirt (18) and the needle receiving port (15) of the holder housing (10) such that the safety shield (50) is capable of being pivoted over at least a portion of the needle (20) received within the needle receiving port (15) of the holder housing (10) (Figs. 1, 2, and 9; page 6, line 30 to page 7, line 9; paragraph [0034]), wherein the safety shield (50) and the collar (30) are axially rotatable with respect to the holder housing (10) about an axis of the holder housing (10), such that the safety shield (50) and the collar (30) can be radially rotated to a desired position around a needle (20) received within the

needle receiving port (15) and around the axis of the holder housing (10) without axial movement of the collar (30) along the axis (Figs. 6 and 7; page 9, lines 14-28; paragraph [0045]).

Dependent claim 2 recites that the collar (30) is annular (page 7, lines 1-2).

Dependent claim 3 is directed to the shield (50) having the features of a rearward end (53), a forward end (54), a longitudinal opening (55) in the forward end (54) for receiving the needle (20), and a hanger bar (51) on the rearward end (53) adapted to connect the safety shield (50) to the collar (30) (Fig. 5; page 8, lines 6-8; paragraph [0039]).

Dependent claim 4 is directed to the collar (30) comprising a hook arm (38) wherein the hook arm (38) engages the hanger bar (51) for connecting the safety shield (50) to the collar (30) whereby there is an interface fit between the hanger bar (51) and the hook arm (38) (Figs. 5 and 6; page 7, lines 18-22; paragraph [0036]).

Dependent claim 5 is directed to an outer surface (37) of the collar (30) including a protrusion (40) and an inner surface of the annular skirt (18) including a groove (19). The groove (19) on the annular skirt (18) is adapted to receive the protrusion (40) on the annular collar (30), thereby providing an interface fit when the collar (30) is received between the annular skirt (18) and the needle receiving port (15) of the holder housing (10) (Figs. 5 and 6; page 9, lines 15-19; paragraph [0045]).

Dependent claim 6 recites that the protrusion (40) is annular and extends around the outer surface of the collar (30) and the groove (19) is annular and extends around the inner surface of the annular skirt (18) (Figs. 5 and 6; page 9, lines 15-19; paragraph [0045]).

Dependent claim 7 is directed to the feature of the annular skirt (18) on the holder housing (10) substantially enclosing an open end of the hook arm (38), thereby preventing the interface fit between the hanger bar (51) and the hook arm (38) from releasing when the collar (30) is received between the annular skirt (18) and the needle receiving port (15) of the holder housing (10) (Fig. 6; page 10, line 4 to page 11, line 4; paragraphs [0046]-[0048]).

Dependent claim 8 is directed to the provision of one or more slits (200) defined in a rearward annular collar section (132) of the collar (130) (Fig. 11; page 11, lines 5-11; paragraph [0049]).

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Dependent claim 9 is directed to the shield (250) and the collar (230) being integral and attached through a living hinge (255) (Fig. 12; page 11, lines 14-27; paragraph [0050]).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Based upon the rejections presented in the final Office Action dated February 10, 2009, Appellants present the grounds of rejection to be reviewed on Appeal:

A. Whether claims 1-2 and 9 were properly rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Hollister '311 in view of Hollister '842.

B. Whether claims 5-6 were properly rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Hollister '311 in view of Hollister '842.

C. Whether claims 3-4 were properly rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Hollister '311 in view of Hollister '842, and further in view of Kobayashi.

D. Whether claims 3-4 were properly rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Hollister '311 in view of Hollister '842, and further in view of Newby.

E. Whether claim 7 was properly rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Hollister '311 in view of Hollister '842, Newby, and further in view of Alesi.

F. Whether claim 7 was properly rejected 35 U.S.C. § 103(a) as being obvious over the combination of Hollister '311 in view of Hollister '842, Kobayashi, and further in view of Alesi.

G. Whether claim 8 was properly rejected under 35 U.S.C. § 103(a) as being obvious over the combination of Hollister '311 in view of Hollister '842, and further in view of Gyure.

VII. ARGUMENT

All of the presently pending claims were improperly rejected in the final Office Action. In general, the Office Action fails to demonstrate a *prima facie* case of obviousness for any of the pending claims.

In order to establish a *prima facie* case of obviousness, the United States Supreme Court in *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 USPQ2d 1385, 1395-97 (2007) identified a number of rationales to support a conclusion of obviousness which are consistent with the proper “functional approach” to the determination of obviousness as laid down in *Graham*. See MPEP § 2143.

The United States Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. § 103 should be made explicit. One exemplary rationale that may support a conclusion of obviousness is that there must be some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention (MPEP § 2143 (G)). Another exemplary rationale that may support a conclusion of obviousness is that the combination of prior art elements according to known methods yields predictable results (MPEP § 2143 (A)). In the present application, the art of record fails to establish a *prima facie* case of obviousness as set forth in *KSR*.

A. Claims 1, 2, and 9 are not rendered obvious under 35 U.S.C. § 103(a) by Hollister ‘311 in view of Hollister ‘842

The combination of Hollister ‘311 with Hollister ‘842 fails to teach and/or render obvious every element of claims 1-2, 5-6, and 9, resulting in a failure to establish a *prima facie* case of obviousness in support of the rejection of claims 1-2, 5-6, and 9. Further, in order to combine Hollister ‘311 and Hollister ‘842, the required modification would result in a change of the functioning of the luer lock system of Hollister ‘842, also resulting in a failure to establish a *prima facie* case of obviousness in support of the rejection of claims 1-2, 5-6, and 9.

In particular, the combination of Hollister ‘311 with Hollister ‘842 fails to provide any suggestion to (A) provide an annular skirt; (B) locate a mounting collar between an annular

skirt and a needle receiving portion of the holder housing; and (C) redesign the relationship between the mounting collar and the holder housing to form an interfitting relationship of the collar with the annular skirt such that the shield can pivot with respect to the collar and the annular skirt. The combination of Hollister '311 with Hollister '842 also fails to meet the requirement for a suggestion or motivation to modify Hollister '311 with Hollister '842 as set forth in MPEP § 2143.01, and fails to meet the requirement for a reasonable expectation of success as set forth in MPEP § 2143.02, as the modification suggested in the Office Action would result in a change in the respective function of Hollister '842.

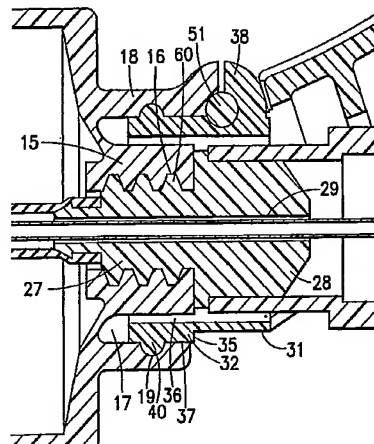
In the final Office Action dated February 10, 2009 ("the Office Action"), Hollister '311 is relied upon as teaching a holder assembly comprising a holder housing (2) and a safety shield (20) pivotably attached to a collar (18) wherein the collar and safety shield are axially rotatable with respect to the holder housing. As discussed at column 3, lines 23-36 of Hollister '311, the receptacle end (6) of the holder housing (2) includes a protuberance or boss (16) about which the collar (18) is fitted via an internal circumferential groove (22).

The Office Action acknowledges that Hollister '311 fails to teach an annular skirt such that the collar can be received between the annular skirt and the needle receiving port of the holder housing. In order to rectify this deficiency, the Office Action relies upon Hollister '842 as disclosing a holder assembly having an annular skirt extending about a receiving port. The Office Action asserts that it would have been obvious to provide the holder assembly of Hollister '311 with an annular skirt such that the collar is received between the annular skirt and the receiving port of the holder housing as taught by Hollister '842 in order to allow an annular protrusion on the collar to externally mate with a holder housing.

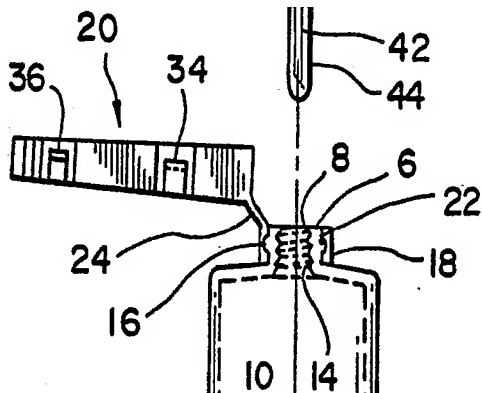
Appellants respectfully disagree with the rejection. Neither Hollister '311 nor Hollister '842 provide any suggestion or motivation for (1) providing a skirt in Hollister '311 and (2) modifying the annular protrusion on the collar to externally mate with this "added" skirt of the holder housing. As discussed briefly above, Hollister '311 teaches that the collar (18) is mounted on the outer surface of the receptacle end (6) of the holder housing (2) via a boss/protuberance (16). As such, in order to perform the combination suggested in the Office

Action, a complete redesign of the holder housing would be required in Hollister '311 in order to be able to locate the mounting collar between an annular skirt and a needle receiving port.

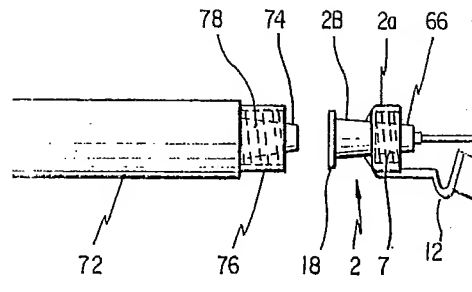
Hollister '842 discloses at column 6, line 62 that the device relied upon in the rejection is a luer lock type syringe (72) comprising an internally threaded collar (76) surrounding its male luer (74). The mating of section (2b) to male luer (74), with the addition of annular collar (76), is achieved by extension (18) at the distal end of section (2b) which threadedly mates with thread (78) at the inner circumference of collar (76). As such, Hollister '842 teaches a completely different device than that shown by Hollister '311. One having ordinary skill in the art would not be motivated to look to the teachings of Hollister '842, which is directed to a luer lock syringe system, when modifying a needle holder assembly such as shown by Hollister '311. Quite simply, Hollister '842 teaches a skirt through collar (76), but such a skirt is to be used for an entirely different purpose, namely, to lock the needle to the syringe device. Such an interlocking engagement that locks the needle to the syringe is very different than the claimed arrangement, where the shield collar is adapted to be rotatable within the annular skirt. The relevant features of the presently claimed invention, Hollister '311, and Hollister '842 are shown below with specific reference to the identified figures and salient features:



Partial view of Figure 6 of Present Invention.
Protrusion (40) of collar (30) interlocks with groove (19) of
holder housing (10) allowing collar (30) to freely rotate
with respect to holder housing (10).



Partial view of Figure 1 of Hollister '311. No skirt. Boss (16) on receptacle end. Interlocks with groove (22) in collar (18).



Partial view of Figure 4 of Hollister '842. Luer lock syringe (72) with internally threaded collar (76) surrounding male luer (74). Threads allow for axial movement of extension (18) with respect to syringe (72) to lock in place. No free rotation of collar with respect to housing.

As set forth in *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1395, a rationale to support a conclusion that a claim would have been obvious is that all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions. As stated above, Hollister '842 is directed to a luer lock syringe (72) including an internally threaded collar (76) surrounding male luer (74). The extension (18) at the distal end of section (2b) moves along these threads (78) at the inner circumference of collar (76) to mate section (2b) with collar (76) and lock the collar in place. With regard to the statement in the Office Action on page 10 that the threads of the annular skirt of Hollister '842 could be modified to include a boss and groove mechanism to allow rotation of the shield/collar assembly, Appellants respectfully disagree. Radial rotation of the safety shield and collar of Hollister '842 about an axis of the holder housing would inevitably result in axial movement of the collar along the axis as extension (18) would travel along thread (78) in an axial direction. Hollister '842 is a luer lock syringe, which is a completely different device than the holder assembly of Hollister '311. Accordingly, Hollister '842 fails to provide any suggestion to modify the threads to include a boss and groove mechanism to allow for rotation of a shield/collar assembly and actually teaches away from any type of radial rotation during use due to the possibility of leakage occurring between the luer

interface of male luer (74) and section (2b), thus rendering the device inoperable. Accordingly, Hollister '842 clearly fails to teach the claimed feature of a safety shield and the collar that are axially rotatable with respect to the holder housing about an axis of the holder housing, such that the safety shield and the collar can be radially rotated to a desired position around a needle received within the needle receiving port and around the axis of the holder housing *without axial movement of the collar along the axis*. The suggested modification of Hollister '311 with Hollister '842 would result in a *change in the functioning* of the luer lock system of Hollister '842 which is contrary to the holding of *KSR International Co. v. Teleflex Inc.*, at 1395.

Furthermore, even if, *arguendo*, one *were* motivated to include the annular skirt of Hollister '842 with the holder assembly of Hollister '311, absent a suggestion to do so as set forth in MPEP § 2143.01 (I), one would **not** be further motivated to redesign the interfitting relationship between the mounting collar and the holder housing of Hollister '311. Such a redesign would require that the shield pivot with respect to the collar and the annular skirt, since such a modification would result in a collar that is axially rotatable along the axis of the holder housing, resulting in a collar/shield that rotates off the holder housing. The modification suggested in the Office Action fails to result in the claimed invention. The Office Action further fails to provide any reasoning as to why one having ordinary skill in the art would provide a skirt on Hollister '311, let alone why one would further modify Hollister '311 so that the annular protrusion on the collar externally mates with the holder housing. Appellants submit that the suggestion or motivation for combining the references to achieve the present invention is gleaned through improper hindsight analysis involving Appellants' disclosure.

Based upon the remarks set forth above, a *prima facie* case of obviousness of claims 1-2 and 9 has not been made. Appellants request that the rejection of claims 1-2 and 9 under 35 U.S.C. § 103(a) in view of the combination of Hollister '311 with Hollister '842 be overturned.

B. Claims 5-6 are not rendered obvious under 35 U.S.C. § 103(a) by Hollister '311 in view of Hollister '842

The combination of Hollister '311 with Hollister '842 fails to teach or render obvious the features of claims 5 and 6. Claim 5 specifically recites that an outer surface of the collar includes a protrusion and an inner surface of the annular skirt includes a groove, wherein the groove on the annular skirt is adapted to receive the protrusion on the annular collar, thereby providing an interface fit when the collar is received between the annular skirt and the needle receiving port of the holder housing. Claim 6 specifically recites that the protrusion is annular and extends around the outer surface of the collar and the groove is annular and extends around the inner surface of the annular skirt. Neither of these features is taught by the combination of Hollister '311 with Hollister '842. Hollister '311 fails to teach an annular skirt, let alone a groove within this annular skirt for cooperation with a protrusion on an outer surface of the collar. Hollister '842 shows *threads* within an annular skirt that cooperate with an extension of a needle adapter. These threads are not equivalent to an annular groove that allows for rotation of a collar *without axial movement of the collar along the axis* of a needle holder, as specifically recited in these claims. Even if one *were* motivated to include the annular skirt of Hollister '842 with the holder assembly of Hollister '311, such a modification would not result in the invention as claimed. Further, neither Hollister '311 nor Hollister '842 provides motivation to redesign the interfitting relationship between the mounting collar and the holder housing, as specifically set forth in claims 5 and 6, so that the shield can pivot with respect to the collar and the annular skirt with the collar axially rotatable within the skirt as set forth in the claims.

Accordingly, the Office Action has not established the asserted *prima facie* case of obviousness based on the cited references. Appellants request that the rejection of claims 1-2, 5-6, and 9 under 35 U.S.C. § 103(a) in view of the combination of Hollister '311 and Hollister '842 be overturned.

C. Claims 3-4 are not rendered obvious under 35 U.S.C. § 103(a) by Hollister '311 in view of Hollister '842 and further in view of Kobayashi

With respect to claims 3-4, the Examiner acknowledges that the combination of Hollister '311 with Hollister '842 fails to teach the claimed features of a pivot assembly wherein a hanger bar is part of the safety shield and a hook arm is part of a collar of claims 3-4. The Office Action relies upon the teachings of Kobayashi as showing a hanger bar (78) attached to a safety shield (70) and a hook arm (36) attached to a collar (30) such that the safety shield (70) pivots about the collar (30). The Office Action asserts on page 5 that it would have been obvious to replace the living hinge of Hollister '311 as modified by Hollister '842 with a pivot assembly comprising a hanger bar attached to a safety shield and a hook arm attached to a collar as taught by Kobayashi as such are art recognized substitutions. The teachings of Kobayashi do not rectify the basic deficiencies of the combination of Hollister '311 and Hollister '842 with respect to independent claim 1 because, like Hollister '842, Kobayashi fails to provide any suggestion to modify Hollister '311 to (A) provide an annular skirt; (B) locate a mounting collar between an annular skirt and a needle receiving portion of the holder housing; and (C) redesign the relationship between the mounting collar and the holder housing to form an interfitting relationship of the collar with the annular skirt such that the shield can pivot with respect to the collar and the annular skirt.

Based upon the remarks set forth above, a *prima facie* case of obviousness of claims 3-4 has not been made. Appellants request that the rejection of claims 3-4 under 35 U.S.C. § 103(a) in view of the combination of Hollister '311 with Hollister '842 and Kobayashi be overturned.

D. Claims 3-4 are not rendered obvious under 35 U.S.C. § 103(a) by Hollister '311 in view of Hollister '842 and further in view of Newby

With respect to claims 3-4, the Examiner acknowledges that the combination of Hollister '311 with Hollister '842 fails to teach the claimed features of a pivot assembly wherein a hanger bar is part of the safety shield and a hook arm is part of a collar of claims 3-4. The Office Action relies upon the teachings of Newby as showing a holder assembly comprising a

hanger bar (182) attached to a safety shield (140) and a hook arm (114) attached to a collar (90) such that the safety shield (140) pivots about the collar (90). The Office Action asserts on page 6 that it would have been obvious to replace the living hinge of Hollister '311 as modified by Hollister '842 with a pivot assembly comprising a hanger bar attached to a safety shield and a hook arm attached to a collar as taught by Newby in order to attach the safety shield to the collar such that the safety shield can pivot with respect to the collar as a holder assembly with a pint hinge or a living hinge is an art recognized substitution. The teachings of Newby do not rectify the basic deficiencies of the combination of Hollister '311 and Hollister '842 with respect to independent claim 1 because, like Hollister '842, Newby fails to provide any suggestion to modify Hollister '311 to (A) provide an annular skirt; (B) locate a mounting collar between an annular skirt and a needle receiving portion of the holder housing; and (C) redesign the relationship between the mounting collar and the holder housing to form an interfitting relationship of the collar with the annular skirt such that the shield can pivot with respect to the collar and the annular skirt.

Based upon the remarks set forth above, a *prima facie* case of obviousness of claims 3-4 has not been made. Appellants request that the rejection of claims 3-4 under 35 U.S.C. § 103(a) in view of the combination of Hollister '311 with Hollister '842 and Newby be overturned.

E. Claim 7 is not rendered obvious under 35 U.S.C. § 103(a) by Hollister '311 in view of Hollister '842, Newby and further in view of Alesi

With respect to claim 7, the Office Action acknowledges that the combination of Hollister '311 with Hollister '842 fails to teach an arrangement wherein the annular skirt on the holder housing substantially encloses an open end of the hook arm. In order to rectify this deficiency, the Office Action relies on Alesi as teaching that it is known to provide a living hinge attached to the annular skirt (8) of the holder housing (2). The Office Action further relies on the teachings of Newby as teaching that hanger bar/hook assemblies are art recognized substitutes for living hinges. The Office Action then asserts on pages 6-7 that it would have been obvious to provide the holder assembly of Hollister '311 as modified by Hollister '842 and Newby with an annular skirt that encloses an open end of the hook arm as claimed in order to achieve a holder

assembly wherein the shield, while only detachably attachable to the collar, also enjoys the characteristics of a full hinge, notably a secure attachment to the housing and collar.

Appellants disagree. None of the cited references disclose or suggest an annular skirt that encloses an open end of a hook arm preventing the release of the interface fit between the hanger bar and the hook arm as recited in claim 7. In particular, the "annular skirt 8" referred to in Alesi does not even enclose the living hinge. Further, Alesi would not motivate one having ordinary skill in the art to position this "annular skirt 8" in the needle holding device of Hollister '311 as modified by Hollister '842 and as further modified by Newby to cooperate with an open end of a hook arm to prevent an interface fit between the hanger bar and the hook arm from releasing when the collar is received between the annular skirt and the needle receiving port of the holder housing. Accordingly, the combination of references fails to teach or render obvious this feature as specifically set forth in claim 7. Further still, the teachings of Newby and/or Alesi do not rectify the basic deficiencies of the combination of Hollister '311 and Hollister '842 with respect to independent claim 1 for the reasons set forth above.

Based upon the remarks set forth above, a *prima facie* case of obviousness of claim 7 has not been made. Appellants request that the rejection of claim 7 under 35 U.S.C. § 103(a) in view of the combination of Hollister '311 with Hollister '842, Newby and Alesi be overturned.

F. Claim 7 is not rendered obvious under 35 U.S.C. § 103(a) by Hollister '311 in view of Hollister '842, Kobayashi and further in view of Alesi

With respect to claim 7, the Office Action acknowledges that the combination of Hollister '311 with Hollister '842 fails to teach an arrangement wherein the annular skirt on the holder housing substantially encloses an open end of the hook arm. In order to rectify this deficiency, the Office Action relies on Alesi as teaching that it is known to provide a living hinge attached to the annular skirt (8) of the holder housing (2). The Office Action further relies on the teachings of Kobayashi as teaching that it is known to provide holder assemblies with a hinge comprising a hook arm attached to a collar and that hanger bar/hook assemblies are art recognized substitutes for living hinges. The Office Action then asserts on page 7 that it would

have been obvious to provide the holder assembly of Hollister '311 as modified by Hollister '842 and Kobayashi with an annular skirt that encloses an open end of the hook arm as claimed in order to achieve a holder assembly wherein the shield, while only detachably attachable to the collar, also enjoys the characteristics of a full hinge, notably a secure attachment to the housing and collar.

Appellants disagree. None of the cited references disclose or suggest an annular skirt that encloses an open end of a hook arm preventing the release of the interface fit between the hanger bar and the hook arm as recited in claim 7. In particular, the "annular skirt 8" referred to in Alesi does not even enclose the living hinge. Further, Alesi would not motivate one having ordinary skill in the art to position this "annular skirt 8" in the needle holding device of Hollister '311 as modified by Hollister '842 and as further modified by Kobayashi to cooperate with an open end of a hook arm to prevent an interface fit between the hanger bar and the hook arm from releasing when the collar is received between the annular skirt and the needle receiving port of the holder housing. Accordingly, the combination of references fails to teach or render obvious this feature as specifically set forth in claim 7. Further still, the teachings of Kobayashi and/or Alesi do not rectify the basic deficiencies of the combination of Hollister '311 and Hollister '842 with respect to independent claim 1 for the reasons set forth above.

Based upon the remarks set forth above, a *prima facie* case of obviousness of claim 7 has not been made. Appellants request that the rejection of claim 7 under 35 U.S.C. § 103(a) in view of the combination of Hollister '311 with Hollister '842, Kobayashi and Alesi be overturned.

G. Claim 8 is not rendered obvious under 35 U.S.C. § 103(a) by Hollister '311 in view of Hollister '842, and further in view of Gyure

With respect to claim 8, the Office Action acknowledges that Hollister '311 as modified by Hollister '842 fails to teach a collar having one or more slits in a rearward portion. To rectify this deficiency, the Office Action relies upon the teachings of Gyure at Figures 3-4; column 3, lines 50-67; and column 4, lines 1-27 to show this feature. Appellants submit that Gyure fails to disclose or suggest slits in a rearward portion of a collar as set forth in claim 8 and

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shown in Figure 11 of the present invention. Gyure discloses providing stepped portions within the hub or collar as shown in Figures 3-4 and stated at column 4, lines 16-20 to vary the inside diameter, but fails to teach slits as asserted by the Office Action. Accordingly, the combination of Hollister '311 with Hollister '842 fails to teach or render obvious this feature as specifically set forth in claim 8. Further still, the teachings of Gyure do not rectify the basic deficiencies of the combination of Hollister '311 and Hollister '842 with respect to independent claim 1 for the reasons set forth above. Appellants request that the rejection of claim 8 under 35 U.S.C. § 103(a) in view of the combination of Hollister '311 and Hollister '842, and further in view of Gyure, be overturned.

VIII. CONCLUSION

For the reasons set forth above, Appellants submit that claims 1-9 are patentable over the cited art and are in condition for allowance. Reversal of all rejections set forth in the final Office Action dated February 10, 2009, and allowance of these claims are respectfully requested.

The Commissioner of Patents and Trademarks is hereby authorized to charge the fee of \$540.00 by credit card, which accompanies this Appeal Brief. However, the Commissioner for Patents is hereby authorized to charge any additional fees which may be required to Deposit Account No. 23-0650. Please refund any overpayment to Deposit Account No. 23-0650.

Respectfully submitted,
THE WEBB LAW FIRM

By  _____

Kirk M. Miles
Registration No. 37,891
Attorney for Appellants
436 Seventh Avenue
700 Koppers Building
Pittsburgh, PA 15219
Telephone: (412) 471-8815
Facsimile: (412) 471-4094
E-mail: webblaw@webblaw.com

CLAIMS APPENDIX

1. A holder assembly comprising:
a holder housing adapted to receive a sample collection tube within a rearward end, a forward end of the holder housing including;
a needle receiving port for receiving a needle cannula therein and
an annular skirt extending about the needle receiving port; and
a safety shield pivotably attached to a collar, said collar having an opening therethrough for receiving a needle cannula therethrough, the collar being received between the annular skirt and the needle receiving port of the holder housing such that the safety shield is capable of being pivoted over at least a portion of a needle received within the needle receiving port of the holder housing,
wherein the safety shield and the collar are axially rotatable with respect to the holder housing about an axis of the holder housing, such that the safety shield and the collar can be radially rotated to a desired position around a needle received within the needle receiving port and around the axis of the holder housing without axial movement of the collar along the axis.
2. The holder assembly of claim 1, wherein the collar is annular.
3. The holder assembly of claim 1, wherein the shield comprises a rearward end, a forward end, a longitudinal opening in the forward end for receiving a needle, and a hanger bar on the rearward end adapted to connect the safety shield to the collar.
4. The holder assembly of claim 3, wherein the collar comprises a hook arm, the hook arm engages the hanger bar for connecting the safety shield to the collar whereby there is an interface fit between the hanger bar and the hook arm.
5. The holder assembly of claim 1, wherein an outer surface of the collar includes a protrusion and an inner surface of the annular skirt includes a groove, the groove on

the annular skirt adapted to receive the protrusion on the annular collar, thereby providing an interface fit when the collar is received between the annular skirt and the needle receiving port of the holder housing.

6. The holder assembly of claim 5, wherein the protrusion is annular and extends around the outer surface of the collar and the groove is annular and extends around the inner surface of the annular skirt.

7. The holder assembly of claim 4, wherein the annular skirt on the holder housing substantially encloses an open end of the hook arm, thereby preventing the interface fit between the hanger bar and the hook arm from releasing when the collar is received between the annular skirt and the needle receiving port of the holder housing.

8. The holder assembly of claim 1, wherein the collar has one or more slits defined in a rearward annular collar section thereof.

9. The holder assembly of claim 1, wherein the shield and the collar are integral and attached through a living hinge.

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